DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 15, 2016

YMed, Inc.
c/o Mr. Thomas P. Schroeder
9951B Business Park Avenue
San Diego, CA 92131

Re: K082343
Trade/Device Name: Vascutrak™ 2 PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: August 13, 2008
Received: August 15, 2008

Dear Mr. Schroeder:

This letter corrects our substantially equivalent letter of September 11, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082343

Device Name: VascuTraK™ 2 PTA Dilatation Catheter

Indications for use: The VascuTraK™ 2 PTA Dilatation Catheter is intended for dilatation of stenoses in the peripheral arteries including the iliac, femoral, popliteal, ilio-femoral, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use: ____X____ AND/OR Over-the-counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahmel
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082343

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510 (k) SUMMARY

Applicant and Manufacturer

YMed, Inc.
9951B Business Park Avenue
San Diego, California 92131
Phone: (858) 549-1337
Fax: (858) 549-1717

Contact Person: Thomas Schroeder, Director, RA/QA

Prepared: August 12, 2008

Common Name: PTA Catheter

Classification Name: Catheter, Angioplasty, Peripheral, Transluminal; Product Code LIT

Proprietary name: VascuTraK™ 2 PTA Dilatation Catheter

Unmodified Device

The VascuTraK™ 2 Catheter is a sterile single use device that consists of a flexible shaft with a single through lumen terminating in a semi-compliant balloon. The catheter has a 24 cm lumen proximal to the balloon that accepts a 0.014" guidewire and an 18 mm lumen distal to the balloon that accepts a 0.014" or 0.018" guidewire. The distal balloon is inflated via a central lumen terminated in a luer fitting at the proximal end. The unmodified device utilizes balloons with diameters up to 4.0 mm and lengths up to 120 mm.

Modified Device Description

The YMed VascuTraK™ 2 PTA Dilatation Catheter is a modification to the VascuTraK™ 2 PTA Dilatation Catheter cleared under K073025. The device is fabricated of the same materials as the unmodified device and has the same intended use.

The distal balloon sizes for the modified device include diameters from 5.0 - 7.0 mm and lengths up to 300mm.

Indications for Use

The VascuTraK™ 2 PTA Dilatation Catheter is intended for dilatation of stenoses in the peripheral arteries including the iliac, femoral, popliteal, ilio-femoral, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics Comparison

The VascuTraK™ 2 PTA Dilatation Catheter is identical in design and construction to the currently marketed VascuTraK™ 2 PTA Dilatation Catheter. This version of the catheter features larger balloons for use in the larger peripheral arteries.

Performance and Safety

No new materials were used for this modification. The biological safety of the device was previously demonstrated through biocompatibility studies of patient contact materials in accordance with the requirements outlined in ISO 10993-1.

The modification does not affect the ability to sterilize the device; thus, the prior sterilization testing is valid. The device conforms to a Sterility Assurance Level (SAL) of 10^{-6}.

The modified device will require a minimum sheath or guide catheter I.D of up to 0.120" depending upon balloon size. The revised labeling reflects the applicable sheath size for the larger balloon sizes.

The modified device was tested using the same test procedures that were used for the unmodified device; these tests included tensile strength, balloon fatigue, compliance and burst. All test results were satisfactory.

The supplied instructions for use provide the user with the applicable warnings and cautions during use. The device is contraindicated for the coronary arteries. There are no new safety or effectiveness issues related to this device. The modified device is considered safe for its intended use.